

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.)
v.)
AMERICAN HOME PRODUCTS)
CORPORATION) NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8441

Bartle, C.J.

March 19, 2010

Deborah K. Hobart-Olson ("Ms. Hobart-Olson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Gary G. Olson, Ms. Hobart-Olson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated September 28, 2004, Dr. Johnson attested in Part II of Ms. Hobart-Olson's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴

3. (...continued)
for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Johnson also attested that claimant suffered from New
(continued...)

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.⁵

In the report of claimant's echocardiogram, Dr. Johnson stated that claimant had "[m]oderate mitral regurgitation." Dr. Johnson did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In April, 2006, the Trust forwarded the claim for review by R. Parker Ward, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Ward concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Ward explained that "[t]race [mitral regurgitation] is present. There is early systolic flow lasting

4. (...continued)

York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

less than 0.1 second consistent with back flow. [There] is trivial sustained [mitral regurgitation].⁶

Based on the auditing cardiologist's finding of physiologic regurgitation,⁷ the Trust issued a post-audit determination denying Ms. Hobart-Olson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also submitted the report of her March 23, 2001 echocardiogram in which the reviewing cardiologist, Shantanu Sinha, M.D., a cardiologist who participated in the Trust's Screening Program,⁹ concluded that Ms. Hobart-Olsen had "moderate mitral

6. Dr. Ward also audited claimant's March 23, 2001 echocardiogram and concluded that "[b]ack flow is seen with no significant sustained [mitral regurgitation]."

7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hobart-Olson's claim.

9. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

regurgitation (2+)." According to claimant, Dr. Sinha's findings, on which claimant relied in her Gray Form to obtain Fund A benefits,¹⁰ provide a reasonable medical basis for Dr. Johnson's representation that claimant had moderate mitral regurgitation.¹¹ In addition, claimant asserted that "quantifying the level of regurgitation shown on an echocardiogram is inherently subjective."¹² Finally, claimant argued that the Trust was not properly applying the "reasonable medical basis" standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.

The Trust then issued a final post-audit determination again denying Ms. Hobart-Olson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See

10. Under the Settlement Agreement, the Gray Form was used to report on echocardiograms performed in the Screening Program. See Settlement Agreement § VI.C.2.g.

11. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to disposition of this show cause claim.

12. In support of this assertion, claimant submitted excerpts from the depositions of five (5) physicians in other proceedings. None of the testimony submitted by claimant, however, addressed Ms. Hobart-Olsen's echocardiogram.

Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Hobart-Olson's claim should be paid. On November 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 20, 2007, and claimant submitted a sur-reply on April 16, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we decide that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we conclude that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Hobart-Olson reasserts the arguments that she made in contest.¹³ In addition, claimant submits that Dr. Ward's findings are inconsistent because he responded that, with respect to claimant's March 23, 2001 echocardiogram, he could not evaluate the level of claimant's mitral regurgitation while he could evaluate the level of claimant's aortic regurgitation.¹⁴ Claimant also contends that an opinion that does not have a reasonable medical basis "equates" to malpractice. Moreover, claimant argues that the Trust did not properly apply the reasonable medical basis standard established in the Settlement Agreement because it encouraged its auditing cardiologists "to deny claims over the slightest difference of subjective opinion." Finally, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of

13. Both claimant and the Trust submit that we should consider Dr. Ward's and Dr. Johnson's conclusions in connection with other claims for Matrix Benefits. As the issue before us is whether there is a reasonable medical basis for Dr. Johnson's representations as to Ms. Hobart-Olsen's medical conditions, Dr. Ward's and Dr. Johnson's determinations in other unrelated claims are not relevant.

14. We disagree. Although Dr. Ward noted in the Auditing Cardiologist Worksheet that the level of claimant's mitral regurgitation on the March 23, 2001 echocardiogram was not evaluable, he concluded that "[b]ack flow is seen with no significant sustained [mitral regurgitation].". Moreover, in the Attestation of Auditing Cardiologist completed in connection with his review of the March 23, 2001 echocardiogram, Dr. Ward stated that "only transient back flow is seen on this study (All in very early systole lasting < 0.1 second). No sustained [mitral regurgitation] is present."

regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard and argues that Dr. Ward properly applied this standard. Moreover, the Trust asserts that the deficiencies of the attesting physician identified by Dr. Ward constitute impermissible conduct as identified by this court in PTO No. 2640 (Nov. 14, 2002). The Trust also contends that claimant cannot rely on the results of a Screening Program echocardiogram to support a claim for Matrix Benefits. Finally, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she did not rebut Dr. Ward's specific findings.

In her sur-reply, claimant challenges the Trust's assertion that excessive gain may have been used in claimant's echocardiogram.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Ward's finding that claimant had only physiologic mitral regurgitation and that Dr. Johnson improperly characterized backflow as mitral regurgitation and failed to examine the regurgitant jet throughout a portion of systole. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Hobart-Olson rests only on Dr. Johnson's check-the-box

diagnosis on her Green Form and the echocardiogram reports for her September 28, 2004 and March 23, 2001 echocardiograms. Ms. Hobart-Olsen does not adequately refute or respond to Dr. Ward's determination that claimant's echocardiogram did not establish moderate mitral regurgitation because the measurement included "early systolic flow lasting less than 0.1 second consistent with back flow."¹⁵ Mere disagreement with the auditing cardiologist is insufficient to meet claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

- (1) failing to review multiple loops and still frames;
- (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram;
- (3) failing to examine the regurgitant jet throughout a portion of systole;
- (4) over-manipulating echocardiogram settings;
- (5) setting a low Nyquist limit;
- (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;
- (7) failing to take a claimant's medical history; and

15. Claimant also asserted, without any medical support, that her "undisputed diagnosis of left atrial enlargement is probative that [she] does indeed have 'moderate' mitral regurgitation." As claimant provided no support or explanation as to how the mere existence of an abnormal left atrial dimension establishes that she has the requisite level of mitral regurgitation, the court does not accept this assertion by claimant.

(8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Ward determined in audit, and Ms. Hobart-Olson does not adequately dispute, that the attesting physician's finding of moderate mitral regurgitation was an erroneous diagnosis due to the improper characterization of normal backflow as mitral regurgitation and the failure to examine the regurgitant jet throughout a portion of systole. Such unacceptable practices by the attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.¹⁶

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Ward determined in audit and Ms. Hobart-Olsen does not adequately dispute that the attesting

16. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Ward merely substituted his opinion for that of the attesting physician. Instead, Dr. Ward specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation based on identified deficiencies, including "early systolic flow lasting less than 0.1 second consistent with back flow." Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to this determination.

physician's finding of moderate mitral regurgitation was erroneous and that claimant's mitral regurgitation was trace. Contrary to claimant's argument, Dr. Ward properly applied the reasonable medical basis standard established under the Settlement Agreement.

In addition, we reject claimant's argument that there must be a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation because there is only "a slight difference of opinion" between the auditing cardiologist and the attesting physician. The Settlement Agreement provides specific criteria to establish moderate mitral regurgitation. Nothing in the Settlement Agreement allows a claimant to recover Matrix Benefits where the claimant relies on a measurement close to that required by the Settlement Agreement. To conclude otherwise would allow claimants who do not have moderate mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement. "A claimant with mitral regurgitation at 19.9% RJA/LAA, a level just below moderate, is ineligible for benefits." PTO No. 2640 at 8 n.5.

Similarly, to the extent claimant argues that inter-reader variability accounts for the difference in the opinions of the attesting physician and auditing cardiologist, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate mitral regurgitation

cannot be medically reasonable where the auditing cardiologist concluded that claimant had only trace, or physiologic, regurgitation. To conclude otherwise would allow a claimant with less than mild regurgitation to receive Matrix Benefits on Level II. This result would render meaningless the standards established in the Settlement Agreement.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because an echocardiogram that was conducted in the Screening Program for Fund A Benefits purportedly supports the attesting physician's conclusion of moderate mitral regurgitation. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix

Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit for all claims for Matrix Benefits. See, e.g., PTO No. 2662 at 13 ("[W]e find that good cause exists under the Settlement Agreement to modify the Trust's procedures to order it to designate all Fund B claims for audit."). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Hobart-Olson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.